

### **Remarks**

This Amendment is in response to the Office Action dated **September 18, 2008**. Claims 1-27, 36 and 37 are pending in this application. The Office Action rejected claims 1-10, 12, 15-21, 23-27, 36 and 37 under 35 USC § 103 over Lee (US 5203777) in view of Kittrell (US 4718417); rejected claim 13 under 35 USC § 103 over Lee in view of Kittrell and further in view of Pacetti (US 6574497); and rejected claims 11, 14 and 22 under 35 USC § 103 over Lee in view of Kittrell and further in view of Armstrong (US 2002/0099431).

By this Amendment, claim 22 is amended for clarification purposes. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

### **Examiner's Interview**

Applicant sincerely thanks Examiner Cheng for the courtesy she extending during the November 3<sup>rd</sup> telephone interview between the Examiner and Applicant's representative, James M. Urzedowski. Though Examiner Cheng and Mr. Urzedowski were unable to come to any agreement regarding the rejections put forth in the Office Action, Applicant greatly appreciates the opportunity to discuss them.

### **Clarifying Amendment**

The dependency of claim 22 has been amended for clarification purposes. Claim 22 recites, "wherein *the symbol* indicates the orientation of the partial graft." Claim 22 previously depended from claim 19, which did not provide an antecedent for "the symbol." Claim 19 recites "a second directional indicator that is offset from the first directional indicator in a circumferential direction." Claim 20 depends from claim 19 and recites, "wherein the first directional indicator and the second directional indicator combine to form *a symbol*." Claim 22 is amended herein to depend from claim 20, which provides antecedent basis for claim 22 and is in accordance with the intended scope of claim 22.

This amendment is non-substantive, and Applicant requests entry of this Amendment After Final.

### Claim Rejections

The Office Action rejected, under 35 USC § 103, claims 1-10, 12, 15-21, 23-27, 36 and 37 under 35 USC § 103 over Lee in view of Kittrell; claim 13 over Lee in view of Kittrell and further in view of Pacetti; and claims 11, 14 and 22 over Lee in view of Kittrell and further in view of Armstrong.

The rejections under 35 USC § 103 are traversed because the applied references do not disclose or suggest the device defined by the rejected claims. The rejection proposes a modification to Lee, however, the modification goes beyond the teachings of the applied references.

The rejections impermissibly use Applicant's disclosure to reconstruct the teachings of Lee, thereby asserting an overly broad interpretation of Lee. The rejection relies on the impermissibly broadened characterization in making the rejections. A person having ordinary skill in the art viewing the applied references without knowledge of Applicant's invention would not have been led to a device described by the pending claims.

When determining obviousness using a combination of references, the prior art must be considered as a whole, without the benefit of the impermissible hindsight vision afforded by the claimed invention. The prior art must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the applicant's invention. Taking into account the evidence of common knowledge and the common sense of the skilled person, there must be some evidence of a suggestion, teaching or motivation that would have led the skilled person to produce the invention as claimed. *In re Translogic Technology Inc.*, 84 USPQ2d 1929, 1937 (Fed. Cir. 2007); *Ortho-Mcneil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2d 1196, 1201-1202 (Fed. Cir. 2008).

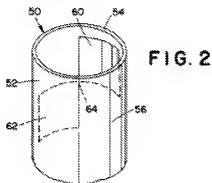
The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007) states: "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. MPEP 2142, discussing

the legal concept of *prima facie* obviousness articulates how the obviousness determination is to be made:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Lee teaches a marking system having a first marker 60 and a second marker 62, wherein the markers 60, 62 are preferably rectangular in shape and made of metal foil. See Figure 2, provided below and column 5, lines 5-14.



Although the rejection asserts that Lee describes the radiopaque markers in an open-ended way, the only type of radiopaque markers that Lee actually teaches is a solid foil/filled polygonal shape. Lee does not disclose or suggest a marker that comprises a wire outline.

The rejection asserts that Lee teaches an equivalence between filled shapes and outlines – “The examiner turns to fig. 4 of Lee to show that a hollow rectangle provides the same function as the filled rectangle....Fig 4 shows that either a filled rectangle or just a boundary of one can be used in Lee, as either fulfills the function (functional equivalents).” See Office Action at page 2. This assertion is traversed, as it can only be reached by impermissibly reading Applicant’s teachings of an outline marker into the Lee disclosure.

Lee cannot teach an equivalence between solid shapes and outlines because it does not disclose or suggest outlines. The assertion of equivalence impermissibly expands the scope of Lee using Applicant's teachings as a roadmap. Although Lee and the present claims both relate to radiopaque markers (e.g. a common genus), Lee teaches a different, specific type (e.g. species) of marker than is recited in the present claims. Lee only teaches foil/solid areas being used for rotational orientation, and does not disclose or suggest a wire outline. The only teaching of using a wire outline to determine rotational orientation appears in Applicant's disclosure, and the rejection impermissibly reads this teaching into the Lee disclosure. Thus, the rejection impermissibly characterizes Lee as teaching both species, when in reality, Lee only teaches the foil/solid species. The characterization of Lee asserted in the rejection fails to step away from Applicant's invention to look objectively at the teachings of Lee for what they would have taught a skilled person at the time of the invention.

In other words, a mere disclosure of Species A in a reference cannot establish that Species A and Species B are functionally equivalent, when the reference does not disclose or suggest Species B. In the present application, Lee cannot establish that solids and outlines are equivalent, when Lee only discusses solids, and the only discussion of outlines is contained in Applicant's teachings.

None of the references applied in the rejections teach a radiopaque marker that comprises a wire outline. Although the rejection cites to Kittrell for the teaching of a wire marker, there is no correlation between the Kittrell wire marker and any shape outline. As previously asserted in the Amendment filed March 11, 2008, Kittrell's teaching of a "wire marker" is limited to a teaching of multiple windings of wire that collectively form a band of material, similar to the band 13h illustrated in Figure 7D. See e.g. column 9, lines 35-39 and Figures 7C and 7D, provided below. Thus, the Kittrell wire windings are collectively equivalent to the solid band marker 13h of Figure 7D.

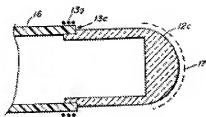


FIG. 7C

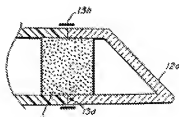


FIG. 7D

Kittrell's mere disclosure of a wound-wire marker band at the end of a catheter provides absolutely no motivation to redesign the Lee foil markers as proposed in the rejection. Lee teaches that a solid area of material provides visibility under fluoroscopy. There is no teaching in Lee or Kittrell that would provide a common sense rationale to a person of skill in the art to replace Lee's foil areas with a wire outline shaped according to the boundary of the foil areas, as proposed in the rejection.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Prior art references must be considered as a whole and suggest the desirability, and thus the obviousness, of making the combination. See *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 221 USPQ 481 488 (Fed. Cir. 1984).

In light of the foregoing remarks, Applicant asserts that the rejection has not presented a clear reason why a person of ordinary skill in the art, when viewing the applied references without hindsight, would have been motivated to replace the solid/foil shapes with outlines as taught by Applicant. Therefore, a *prima facie* case of unpatentability has not been presented under 35 USC § 103 against independent claims 1, 15, 36 or 37. Each pending dependent claim is patentable over the applied references for at least the reasons discussed with respect to the independent claim from which it depends.

Pacetti was cited against dependent claim 13 for its teachings relevant to MRI markers. See Office Action at page 4. The addition of Pacetti does not remedy the shortcomings of the rejection discussed above. Pacetti does not provide any motivation to modify Lee or Kittrell in a way that would arrive at a modified device meeting the limitations of the rejected claims.

Armstrong was cited against dependent claims 11, 14 and 22 for the purpose of teaching a graft; however, the rejection does not provide any correlation between Armstrong's general teaching of a graft and the specifics of the rejected claims, which are directed to oriented grafts with relation to the rotational outline markers discussed herein.

Accordingly, Applicant requests withdrawal of the rejections under 35 USC § 103.

Respectfully submitted,

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